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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/011,910	02/17/1998	SERGIO ABRIGNANI	0336.001	1499

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EXAMINER

BRUMBACK, BRENDA G

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 07/17/2002

26

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/011,910

Applicant(s)

ABRIGNANI, SERGIO

Examiner

Brenda G. Brumback

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03/04/02 & 05/21/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,4,7-10 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3, 4, 7-10, and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This action is responsive to the amendments filed 03/04/02 and 05/21/02. Claim 2 was canceled. Claims 3, 4, 7-10, and 17 are pending and under examination on the merits.

#### ***Specification***

The objection to the disclosure for the page numbers of the Table of Contents (pages 12-13) is withdrawn pursuant to applicant's amendment thereof.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 3-4, 7-10, and 17 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (the "written description" rejection) is maintained for the reasons of record.

Applicant's arguments have been fully considered but they are not persuasive for the following reasons.

Applicant argues that one does not need a sequence for the 24kd protein which specifically binds to the E2 protein of hepatitis C virus (HCV) to be in possession of the claimed fragments and variants and cites a reference teaching chemical modification of proteins by group specific and site-specific reagents. Applicant's argument and the cited reference are persuasive for the claimed fragments of the 24 kd protein which specifically bind the E2 protein of HCV, however, they are not persuasive for the claimed variants. Applicant's arguments are limited to cleavage products (fragments), wherein the claims are drawn to the genus comprising the 24kd protein and functionally equivalent variants of the protein which bind the E2 protein of HCV, as well as fragments of the protein. Such variants are not described in applicant's disclosure. As was set forth in the previous Office action, applicant's disclosure defines a

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functional variant as a chemical modification of the 24kd protein which may include one or more insertions, deletions, or replaced amino acids. There is no description of the amino acid sequence of the 24 kd protein. There is no description of any such amino acid insertions, deletions, or replacements. Consequently, one skilled in the relevant art would not recognize from the disclosure that applicant was in possession of the claimed genus comprising such variants.

The rejection of claims 3-4, 7-10, and 17 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process for a protein having a molecular weight of about 24kd, does not reasonably provide enablement for functionally equivalent variants and fragments thereof is withdrawn for functionally equivalent fragments and is maintained for functionally equivalent variants.

Applicant argues that one would be able to produce functionally equivalent variants or fragments of the 24kd protein without undue experimentation in light of the state of the art of protein chemistry. While applicant's argument is persuasive for fragments of the 24kd, the argument is not persuasive for functionally equivalent variants. As was set forth *supra*, applicant's disclosure defines a variant as having one or more deletions, insertions, or substitutions in the amino acid sequence. Neither the art nor applicant's specification teaches the amino acid sequence of the 24kd protein and neither teaches or provides guidance as to what amino acids may be deleted, inserted, or substituted without altering the function of HCV E2 binding specificity. Given the teachings of unpredictability found in the art regarding amino acid substitutions, insertions, and deletions and maintenance of protein function, which were set for the in the previous Office action, and in the absence of sufficient guidance in applicant's disclosure to overcome those teachings of unpredictability, it would require undue experimentation by the skilled artisan to make and use the claimed variants.

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The rejection of claims 3-4, 7-10, and 17 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive. Applicant argues that "all" functionally equivalent variants are being claimed; however, the specification fails to teach the metes and bounds of the claimed variants because it fails to teach the amino acid sequence of the 24kd protein. Thus, it must of necessity also fail to teach the insertions, additions, or deletions to the amino acid sequence of the 24kd protein which are encompassed within the definition of a functional variant. Absent such disclosure, the metes and bounds of the claimed variants cannot be determined and the claims are indefinite.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to

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Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

BB

July 16, 2002

*Brenda Brumback*  
Brenda Brumback  
Primary Examiner